# Cost-Effectiveness of Percutaneous Automated Lumbar Nucleotomy

## Comparison with Traditional Macro-Procedure Discectomy

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**Key words**: spine, intervertebral disc hernia, nucleotomy, discectomy, cost-effectiveness

***Summary***

*This study was conducted in order to evaluate the cost-effectiveness of percutaneous automated lumbar nucleotomy in comparison with traditional macro-procedure discectomy in the treatment of herniated discs.*

*Sixty-eight patients undergoing surgical procedures and 90 treated with nucleotomy were consecutively included. Both cohorts were assessed pre-operatively and at regular intervals for one year or more after treatment by independent observers, using a clinical overall scoring system (COS) with 0 being the best attainable result and 1000 the poorest conceivable status of the patients.*

*There were better clinical results after surgery with 78% successes after one year compared to 62% after nucleotomy. By including subsequent operations and re-operations after failure to respond to the primary treatment, the success rates rose to 79% and 77%, respectively.*

*The cost of surgical treatment was calculated to USD 6.119 per patient and the cost of a nucleotomy procedure was USD 1.252. Owing to an almost five times higher price of surgery than nucleotomy, the latter turned out to be 2.7 to 3.9 times more cost-effective, depending on whether secondary treatment was included or not. Due to the minimal difference in final outcome between the groups, however, the marginal cost per extra success in patients primarily treated with surgery was as high as USD 205.850.*

*The study concludes that nucleotomy, as a mini-invasive procedure with low complication rates and the potential of a quick recovery, is more cost-effective than traditional surgical treatment for lumbar disc herniation.*

## Introduction

A variety of publications have shown that surgical removal of herniated disc material followed by evacuation of the nucleus pulposus is an effective treatment alternative with success rates in the 65-95% range [1,2].

With improvement in surgical techniques, and by using microscopes [2,3], less traumatic operations could be carried out, with decreased complication rates and a potentially quicker recovery. However, all surgical procedures carry a certain risk of failed back surgery syndrome [4]. Re-operation rates as high as 18% within 5-10 years have been reported [5]. Owing to the risk of failed lumbar disc surgery, a search for less invasive treatment of hernias entailed the introduction of chymopapain in 1964 [6] and percutaneous lumbar nucleotomy in 1975 [7]. These techniques avoid the risk of general anaesthesia, delayed bony instability and epidural fibrosis associated with conventional surgery, and may result in an earlier return to work.

An automated device for nucleotomy was developed in 1985 [8]. The use of this equipment normally entails minimal tissue damage [9] and treatment on an out-patient basis is possible. Satisfactory outcomes in 60-85% of the patients have been reported in the majority of publications [10-16]. However, both the effectiveness [17] and the cost-effectiveness [18] of percutaneous nucleotomy has been questioned due to exceptionally poor clinical results in these two studies.

At Ullevaal University Hospital separate studies were conducted to evaluate the treatment outcome of traditional macro-procedure surgical discectomy [1] and automated percutaneous nucleotomy [12,13] with the automated Nucleotome R system (Surgical Dynamics Inc., Alameda, Ca.) [8].

The patients of both studies were evaluated with the same methods with respect to preoperative disability and the clinical result. Hence, data are sufficient and adequate for a comparison of the two treatment modalities with respect to effectiveness and cost-effectiveness, which is the aim of the present investigation.

## Patients and Methods

The population treated with traditional macro-procedure operations comprised 68 patients, 30 women and 38 men, aged 18-65 years at the time of surgery (mean 41.8 years, SD 11.2). The nucleotomy group consists of 90 patients, 44 women and 46 men aged 18-68 years (mean 38.8 years, SD 11.4) at the time of nucleotomy. Age and sex distribution are therefore similar in the two groups. Other background variables known to be risk factors of the outcome of spinal intervention were also similar and appear in table 1.

All patients of both groups had sciatica corresponding to radiolologic findings.

*Clinical Evaluation. The Clinical Overall Score (COS)*

The patients were examined before and at regular intervals for one year or more after treatment. Comparison of the one-year outcome has been used in this study. All assessments were carried out by independent observers.

As described in detail elsewhere [1,19], a clinical overall scoring system included the following four assessments was used: pain intensity, physical examination, functional status according to the Oswestry Low Back Disability Questionnaire [20] and the consumption of analgesics. The COS was defined as the weighted sum of these four subsets, with a maximum score of 1000 representing the worst conceivable status of the patient and 0 being the best attainable treatment outcome.

As in another study [19] we also used COS as a dichotomous variable, defining an outcome of less than 250 as a success, whereas higher scores were considered failures.

*Lumbar Percutaneous Automated Nucleotomy*

With a few modifications [21], the technique designed and described by Onik et Al [8] was used. Under C-arm fluoroscopic control all nucleotomies were conducted in the myelography room of the radiology department. The patients were treated awake on an out-patient basis under analgesia and sedation. After the intervention, they were observed in the hospital for six hours, treated with anti-inflammatory medication for three days and were advised to avoid lifting, bending and abundant sitting for one to three weeks.

*Surgical Techniques*

All patients were treated with a conventional macrodiscectomy procedure. Fifty-seven had partial and 11 had a full laminectomy followed by removal of the herniated nucleus and evacuation of the disc content. The surgical patients were also advised to avoid lifting, bending and abundant sitting postoperatively. They followed the same routine for six weeks with subsequent referrals to their general practitioners.

## Calculation of Costs

*Surgical Discectomy.* The diagnosis related group (DRG) factor of traditional laminectomy with evacuation of the disc content is 1.68 and the price per DRG unit 3.636 USD, resulting in a cost of USD 6.119 per operation according to The Norwegian Ministry of Health and Social Affairs.

*Automated Percutaneous Nucleotomy* costs have been calculated to USD 1.252, of which the nucleotomy equipment accounts for USD 820 and other costs including the fee for a radiologist and a radiographer, and the use of a X-ray lab and other equipment are USD 432.

Cost-effectiveness for each treatment alternative was calculated both in terms of average costs per successful treatment and costs per

Table 1 **Baseline characteristics in 90 patients ( 44 women and 46 men ) treated with nucleotomy and 68 patients (30 women and 38 men) treated with macrodiscectomy**

| | Nucleotomy (n=90) | | | Macrodiscectomy (n=68) | | |
|---|---|---|---|---|---|---|
| | **Mean** | **Range** | **SD** | **Mean** | **Range** | **SD** |
| Age ( years) | 38.8 | 18-68 | 11.4 | 41.9 | 18-65 | 11.2 |
| Height (m) | 1.76 | 1.56-1.95 | 0.09 | 1.76 | 1.56-1.96 | 0.09 |
| Weight (kg) | 74.6 | 44-106 | 14.0 | 73.4 | 51-102 | 11.9 |
| Body mass index (kg/**m) | 23.9 | 16-38 | 3.5 | 23.6 | 17-33 | 2.8 |
| Months with sciatica | 8.1 | 1-50 | 8.7 | 8.1 | 1-99 | 12.9 |

Table 2 **Clinical status before and one year after macrodiscectomy and nucleotomy**

| Treatment modality | COS before treatment | | COS one year after treatment (Re-op. included) | | Postop. reduction of COS (Re-op. included) | | Pat. with COS <250 (=successes) Re-operations included | | Primary treatment only | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Range** | **Mean (SD)** | **Range** | **Mean (SD)** | **Red. of mean** | **%** | **No.** | **%** | **No.** | **%** |
| *Discectomy:* All (n=68) 1) | 232 - 836 | 542 (133) | 0-740 | 140 (168) | 402 | 74 | 54 | 79 | 53 | 78 |
| Non-contained (n=36) 2) | 232 - 836 | 544 (162) | 0-564 | 147 (172) | 397 | 73 | 26 | 72 | 26 | 72 |
| Contained (n=32) 3) | 380 - 736 | 541 (95) | 0-740 | 133 (167) | 408 | 75 | 28 | 88 | 27 | 84 |
| *Nucleotomy:* (n=90) 4) | 172 - 836 | 488 (128) | 0-500 | 164 (133) | 324 | 66 | 69 | 77 | 56 | 62 |

*1-4): No. of operations (4) and re-operations (1-3) due to failed primary treatment:*
*1): 3 re-operations; 1 success and 2 failures*
*2): 1 unsuccessful re-operation*
*3): 2 re-operations: 1 success and 1 failure*
*4): 15 operations after failed nucleotomy: 13 successes and 2 failures.*

point and % reduction of COS as a continuous variable. Marginal costs per extra success obtained by one of the alternatives compared to the other were also calculated [22].

## Imaging

Pre-treatment imaging was done with CT using a GE 9800 Quick unit (General Electric). Six contiguous 5 mm slices were obtained through each of the lower three lumbar disc spaces and adjacent vertebra at 120 kV, 170 mA and a scan time of 3 s. The axial images were recorded with a window width of 400 and level of 50 Hounsfield Units (H.U.) for the study of soft tissue and with 2000 and 400 H.U. for bony details.

The disc hernias of the surgical patients were classified into two categories: contained or non-contained. They were classified as non-contained if one or more of the following generally accepted criteria were present: irregular or indistinct margins [23], sharp angle towards the base of the maternal disc [24,25], location in the lateral recesses [25], size exceeding 50% of the diameter of the thecal sac [26], or cranial or caudal migration away from the disc space [23,26]. According to these criteria, 36 of the surgical patients harboured non-contained hernias whereas 32 had contained hernias. By contrast, contained hernias should only be observed at the disc level. They have smooth and well-defined margins.

The division of the surgical patients into two groups was done in order to avoid the potential methodological error of comparing the results of surgery of a group of patients not suited for nucleotomy with the nucleotomy outcome of a different population.

## Results

### *Clinical Results*

The clinical results one year after treatment appear in table 2, which also displays the pre-operative disability. It appears that patients treated with surgery were minimally more disabled pre-operatively than the nucleotomy population.

No significant difference was noted between surgical patients with contained and those with non-contained hernias, either before or one year after treatment. By that time an average reduction of 74% in the COS was found after surgery compared to only 66% in patients treated with nucleotomy. As a consequence, the nucleotomy group had a marginally higher mean COS one year after treatment than patients undergoing traditional discectomy. Using COS as a dichotomous variable with a cut-off point of 250, this tendency is confirmed. By doing so, however, the difference in outcome scores between contained and non-contained hernias appears to be bigger than expected according to the COS score.

Excluding the beneficial effect of subsequent operations on 15 patients in the nucleotomy group and re-operations of three surgical patients after unsuccessful primary operations, the difference between 78% success after primary surgical treatment compared to only 62% following nucleotomy is borderline significant ($p= 0.05$). In this situation, the difference between contained and non-contained hernias in the surgical group remains non-significant ($p= 0.36$).

## Cost-Effectiveness

### *Primary Treatment and Subsequent Operation or Re-operation*

In table 3 the costs of primary and secondary treatment have been calculated both in terms of costs per successfully treated patient using COS as a dichotomous variable, as well as costs relative to the reduction of COS as a continuous variable.

It turns out that the higher success-rates of surgical treatment compared to nucleotomy by far compensates its almost five times higher costs. The average cost per success in the nucleotomy group is only 36% of that of surgery, re-operations included. Conversely, with nucleotomy the cost per point reduction of COS is only 44% and per cent reduction only 40% of the corresponding surgical costs.

### *Marginal Costs*

When re-operations were included, patients primarily treated with surgery had a success-rate of 79% compared to 77% in those primarily treated with nucleotomy (table 2). The average cost per surgical patient was USD 6.389 and per nucleotomy patient USD 2.272 (table 3). The marginal cost per extra success choosing surgery as the primary treatment modality is calculated as follows:

**USD (6.389-2.272)/0,79-0,77=USD (4.117/0,02)=USD 205.850**

### *Primary Treatment Only*

Since repeated pre-operative calculation of COS was not performed in all failures who had a second spinal intervention within a year, calculation of cost-effectiveness of the primary treatment could only be based on the distinction between success and failure (table 4). It appears that the price of a success following traditional surgical discectomy is almost four times higher than for nucleotomy.

## Discussion

### *Patient Population*

It may be argued that only patients with contained hernias demonstrated by imaging techniques should have been included in the comparisons. However, since a separate previous study[27] showed no significant influence of pre-operative CT-features on the treatment outcome in the macrosurgical cohort, all surgical patients were included, but divided into two groups according to the distinction between contained and non-contained hernias.

### *Cost-Effectiveness and Effectiveness*

As expected, nucleotomy was less effective than surgical treatment. However, owing to a difference in costs approaching a factor of five in favour of nucleotomy, this treatment turned

Table 3 **Cost-effectiveness calculations of primary treatment and subsequent operation or re-operation**

| | | |
|---|---|---|
| Surgical discectomy | (n=68, including 3 re-operations) | |
| All: | Total costs (68+3) x USD 6.119 | = USD 434.449 |
| | Cost per patient: USD 434.449 : 68 | = USD 6.389 |
| | Cost per success: USD 434.449 : 54 | = USD 8.045 |
| | Cost per point reduction in COS: 6.389 : 402 | = USD 15,89 |
| | Cost per % reduction of COS 6.389 : 74 | = USD 86,33 |
| Non-contained hernias: | (n=36, including 1 re-operation) | |
| | Total costs (36+1) x USD 6.119 | = USD 226.403 |
| | Cost per patient: USD 226.403 : 36 | = USD 6.288 |
| | Cost per success: USD 226.403 : 26 | = USD 8.708 |
| | Cost per point reduction in COS: 6.288 : 397 | = USD 15,83 |
| | Cost per % reduction of COS 6.288 : 73 | = USD 86,13 |
| Contained hernias: | (n=32, including 2 re-operations) | |
| | Total costs (32+2) x USD 6.119 | = USD 208.046 |
| | Cost per patient: USD 208.046 : 32 | = USD 6.501 |
| | Cost per success: USD 208.046 : 28 | = USD 7.430 |
| | Cost per point reduction in COS: 6.501 : 408 | = USD 15,93 |
| | Cost per % reduction of COS 6.501 : 75 | = USD 86,68 |
| Percutaneous nucleotomy | (n=90, followed by 15 operations) | |
| | 90 x USD 1.252 | = USD 112.680 |
| | +15 x USD 6.119 | = USD 91.785 |
| | Total costs nucleotomy and subsequent surgery | = USD 204.465 |
| | Cost per patient: USD 204.465 : 90 | = USD 2.272 |
| | Cost per success: USD 204.465 : 69 | = USD 2.963 |
| | Cost per point reduction in COS: 2.272 : 324 | = USD 7,01 |
| | Cost per % reduction of COS: 2.272 : 66 | = USD 34,42 |

out to be three to four times more cost-effective, depending on whether or not re-operations were included.

However, in the decision-making between different treatment alternatives, the marginal costs of improving the outcome by choosing a particular treatment alternative are considered more important than the average costs [22]. Owing to the minimal difference in outcome in favour of surgery in this study and a big difference in costs, the marginal costs of choosing surgery turned out to be extremely high when re-operations were included.

It may be argued that the results of the primary treatment only are more important than the combined results of primary treatment and additional operations and re-operations. This may hold true if nucleotomy is regarded as a separate and ultimate treatment alternative, as advocated by some authors [28]. However, our strategy has been to choose nucleotomy as a first step treatment alternative in selected patients in order to avoid surgery in a substantial number. According to this strategy, it appears to be more correct to include the secondary treatment in the calculations.

Table 4 **Cost-effectiveness calculations of primary treatment only**

| | | |
|---|---|---|
| Surgical discectomy | | |
| All (n=68) | Total costs 68 x USD 6.119 | = USD 416.092 |
| | Cost per success: USD 416.092 : 53 | = USD 7.850 |
| Non-contained hernias: | | |
| (n=36) | Total costs 36 x USD 6.119 | = USD 220.284 |
| | Cost per success: USD 220.284 : 26 | = USD 8.472 |
| Contained hernias: | | |
| (n=32) | Total costs 32 x USD 6.119 | = USD 195.808 |
| | Cost per success: USD 195.808 : 27 | = USD 7.252 |
| Percutaneous nucleotomy | | |
| (n=90) | Total costs 90 x USD 1.252 | = USD 112.680 |
| | Cost per success: USD 112.680 : 56 | = USD 2.012 |

It may be easy to decide which treatment to choose as the primary modality if the most effective treatment also turns out to be the most cost-effective alternative. However, a situation like the one encountered in this study, with the least effective treatment being the far most cost-effective, may entail an ethical conflict.

Other factors that may be included in the decision-making include local experience, complication rates and adverse effects of various treatments. As shown previously [29], nucleotomy has very low complication rates. Further, it avoids the risk of the failed back surgery syndrome which may cause life-long severe disability [4]. Therefore, even with lower primary success rates, it may be justifiable to choose nucleotomy as the primary treatment modality in selected patients. Subsequent surgical discectomies seem to be necessary in only 20-25% of the patients, reducing the risk of the failed back surgery syndrome accordingly. This policy may be further supported by the superior cost-effectiveness of nucleotomy as shown in this study.

*Recovery*

Successfully treated patients returned to work at an average of 54 days after nucleotomy (range 2-150 days). This is a significantly shorter period than may be expected after traditional surgery. However, the corresponding data in surgical patients of this study have not been recorded in sufficient detail for exact comparison.

The potential of a quicker recovery after percutaneous nucleotomy has also been demonstrated by the remarkably short sick-leave periods of some large materials in the USA, with 70% return to work at an average of two weeks after treatment [11,14]. For patients in private pay even more impressive data have been published, with a return to work at an average of 3-5 days [14]. This is quite different from our experience, with a much longer average sick-leave period. This may reflect differences in the preoperative disability of the patients, as well as effects of various social security systems in different countries.

*Possible Effect of the Surgical Technique*

Published data indicate that microdiscectomy may be associated with less tissue damage, fewer complications and at least equally good results compared to traditional macro-procedures with laminectomy. Since most patients suitable for nucleotomy are also suitable for the microsurgical technique, it may be argued that a comparison between these methods is more adequate than the present comparison between nucleotomy and macrodiscectomy.

*Outcome Assessment*

There is no generally accepted and standardized method for the assessment of outcome of lumbar disc surgery. The clinical overall scoring system has proven easy to use, and the results have correlated closely with the patient's own opinion of the outcome [1,30]. However, the outcome assessment may heavily depend on the actual evaluation method. Using 15 different evaluation methods a variation in success rates after spinal surgery of more than 20% was noted by Korres et Al [31].

## Conclusions

Despite higher success rates in surgical discectomy than automated percutaneous nucleotomy, nucleotomy is significantly more cost-effective both in terms of primary cure and when secondary treatment is included.

## Acknowledgement

The help and advice of Tor Iversen, PhD., Centre for Health Administration, The National Hospital, Oslo, is gratefully acknowledged.

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## EDITORIAL COMMENT

*Since these costs may differ widely, it is, in principle, not correct to list the exact costs of device minutes and material used in automated nucleotomy but just give a rough estimate of the costs for surgery that are also determined by operation time in minutes as well as material used and personnel involved. Such a comparison should not be based on mean values per federal state or country, but a mean value should be determined for each hospital, since the course of automated nucleotomy is specified in detail.*

*When comparing the surgical procedures applied, it is remarkable that completely antiquated ones like hemilaminectomy, partial laminectomy or complete laminectomy are applied and compared to a procedure that relieves pressure in the intervertebral or disc space and never removes more than 1g of tissue. It must also be remembered that a disc prolapse represents a particular point of time in the course of total vertebral degeneration, and more extensive findings which then add osteochondrotic alterations to the root compression usually require open surgery.*

*The surgical methods described here seem antiquated and should be replaced by modern macrodiscectomy under the microscope. Furthermore, automated nucleotomy involves disposable material, which will then increase costs to more $1,000 per intervention.*

*In the meantime, there are endoscopic techniques that are of course not CT controlled, since they are minimal invasive procedures of a surgical nature and performed in the operating theatre, and the material used is usually not disposable but can be resterilized and is thus clearly less expensive. Furthermore, the tendency in the past few years has been to give preference to fewer rather than more invasive interventions. This does not imply that something like percutaneous automated lumbar nucleotomy is performed because the indication is not completely waterproof, as it should be for vertebral interventions. A comparison and summary of cases, also in our department, with up to five re-interventions for a disc prolapse as well as for associated lumbar pain or root compression syndrome, reveals that one thing remains the same: the first indication for surgery was wrong. This is a common feature of all these cases and leads to the second point I would like to comment on briefly.*

*Spinal neurosurgeons and orthopaedic surgeons have been fighting for a number of years for a specialist in vertebral surgery. At the present time, I absolutely disagree that radiologists not exclusively involved in spinal matters should be therapeutically active. This would be different, for example, with interventional spinal radiologists, whom one would want to integrate in a group of vertebral surgeons. As we all know from experience, this is not the case. Disposable sets used for CTs are "tried out" by radiologists here, often without a correct indication or a lot of experience in spinal surgery. Thus, despite my reserve, I am quite willing to expand my knowledge, and if there really are people specifically interested in spinal interventional radiology, who would concentrate on these patients, they should be included in the group of vertebral surgeons. I very much hope that the World Congress on Spinal Surgery we are organizing for the year 2000 will be a step in this direction that may one day lead to the acceptance of an independent specialist for vertebral diseases and vertebral surgery.*

J. Meisel